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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,202	09/11/2003	Orn Almarsson	TPI-350C1	6536

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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,202	ALMARSSON ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *3-8 and 12-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/20/03,4/5/04,6/21/04,9/2/04,8/31/06 and 9/21/06.

DETAILED ACTION

Claims 1-37 are pending in the application, with claims 3-8 and 12-36 having been withdrawn as drawn to a non-elected invention. Accordingly, claims 1-2, 9-11 and 37 are being examined on the merits herein.

Election/Restrictions

Applicant's election of the claims of Group I, namely claims 1-2, 9-11 and 37 in the reply filed on January 8, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 3-8 and 12-36 are being withdrawn from examination as being drawn to non-elected inventions

Priority

Applicants' claim of priority as a CIP of PCT/US03/27772 filed September 4, 2003, which is a CIP of 10/378,956, filed March 3, 2003, and claim of priority as a CIP of application serial nos. 10/367,829, 10/449,307 and 10/601,092, as well as the priority claims to the provisional and non-provisional applications to which these application claim priority, is acknowledged.

However, Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 or 119(e) as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, including application nos. 10/378,956, 10/367,829, 10/449,307 and 10/601,092, as well as the provisional and non-provisional applications to which they claim priority, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In particular, these prior applications do not provide adequate support for all pharmaceutical co-crystal compositions in general having an API that is a liquid or a solid at room temperature, and a co-crystal former that is solid at room temperature, where the API and co-crystal former are hydrogen bonded to each other, as recited in claim 1. The prior applications also do not teach all of the specific co-crystal formers as recited in claim 2, all of the specific co-crystal API and co-crystal former combinations as in claim 11, and also do not teach all of the exceptions as listed

in claim 37. Instead, U.S. Patent Application Serial No. 10/378,956, for example, discloses that co-crystals can comprise specific co-crystal combinations such as carbamazepine and nicotinamide, but does not disclose the general co-crystal formulations as recited in claims 1-2, 9-10, and 37, and also does not disclose certain specific co-crystal combinations as recited in claim 11, such as modafinil and mandelic acid. Accordingly, the instant claims do not receive benefit of the filing dates of these prior applications or the provisional and non-provisional application to which they claim priority.

The claims are fully supported under 35 U.S.C. 112, first paragraph, by the PCT application No. PCT/US03/27772, filed September 4, 2003, and thus receive benefit of the filing date of the PCT application. Accordingly, the instant claims are granted the effective filing date of September 4, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

Claims 1-2, 9-10 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, Applicants have only shown the formation of the particular co-crystals recited in claim 11, such as for example crystals of cabamazepine and saccharin, but do not exemplify or otherwise show the formation of all co-crystals containing any solid API and any co-crystal former that is liquid or solid, and where the components are hydrogen bonded to one another, or co-crystals with any of the numerous and divers different co-crystal formers in claim 2 or APIs as in claim 9. Applicants have not described or shown how the numerous and diverse different co-crystals as claimed could be obtained.

The specification only describes the preparation of the particular co-crystals recited in claim 11 (see pages 7-10, in particular.) Accordingly, the specification does not describe the claimed subject matter in a manner sufficient to convey to one of ordinary skill in art that the inventors were in possession of the entire invention, including the formation of co-crystals containing any API and any co-crystal former that are hydrogen bonded and are solid or liquid, as recited in the claims.

Enablement Rejection

Claims 1-2, 9-10 and 37 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement for the full scope of the claims. The specification is enabling for the preparation and use of the particular pharmaceutical co-crystals as recited in claim 11, such as co-crystals of carbamazepine and saccharin, or celecoxib and nicotinamide. However, the specification is not enabling for the preparation of all co-crystals having any API that is solid, and any co-crystal former that solid and liquid, where the components are hydrogen bonded to one another, as recited in claim 1, or all co-crystals having the numerous and diverse APIs and co-crystal formers as in claims 2, 9-10 and 37.

The instant specification fails to provide information that would allow the skilled artisan to fully make and use the instant invention without ***undue experimentation.*** Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the

court set fourth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1. The nature of the invention: The instant invention pertains a co-crystal composition containing a solid API and a solid or liquid co-crystal former, where the API and co-crystal former are hydrogen bonded to one another.

2. The state of the prior art: The skilled artisan would view the formation of different crystalline forms as being unpredictable due to the numerous different crystallization factors needing to be controlled to provide different crystal states, as well as the unpredictability in predicting the different types of crystals that may exist. For example, as disclosed by Angelo Gavezzotti ("Are Crystal Structures Predictable?" by Gavezzotti, Acc. Chem. Res, 1994, Vol. 27, pages 309-314), the formation and structure of crystals is unpredictable at best (see first full paragraph, in particular.) Gavezzotti teaches that it can be unpredictable whether compounds will crystallize at all, crystal growth from solution is known to be problematic, and in general "a crystal is

more readily destroyed than built" (see first full paragraph of right hand column on page 309.) Thus, Gavezzotti teaches that the production of crystals is unpredictable at best, with the particular process parameters suitable for crystallizing a compound typically not being known in advance, and thus desired crystals can generally only be arrived at via experimentation and dealing with "tough problems in the control of solidification, crystal growth, and crystal morphology, mainly due to perverse kinetic control of nucleation (see first full paragraph of right hand column on page 309.)

3. The relative skill of those in the art: the relative skill of those in the art is typically very high, i.e. experienced scientists having advanced degrees in the chemical and biochemical fields.

4. The predictability of the art: As discussed above, the production of crystal forms is highly unpredictable, with crystal growth from solution being problematic. (see see page 309 of Gavezzotti, in particular.)

5. The breadth of the claims: the unpredictable nature of the invention is exacerbated by the breadth of the claims. The claims require co-crystal composition that has any API that is solid, in general, with any crystal co-former that is solid or liquid, in general, where the components are hydrogen bonded, as in claim 1. Thus, the claims as instantly presented encompass all co-crystals having any solid API and any

solid or liquid co-crystal former, where the component are hydrogen bonded to one another.

6. The amount of direction or guidance presented: the specification does not provide any direction or guidance as to how to go about manufacturing and/or finding all of the different crystal forms that contain an API and a co-crystal former and that are hydrogen bonded to one another, and that thus fall within the scope of the claim. The specification generally teaches that hydrogen bonding is a dominant interaction in the formation of a co-crystal (see page 10 of specification, in particular), but does not teach how one of ordinary skill in the art would go about finding the proper crystallization process parameters, such as the proper crystallization solvent, temperature, etc, to allow for the formation of all of the co-crystals encompassed by the claims, without requiring undue experimentation.

7. The presence or absence of working examples: The specification does not provide working examples that are sufficient to show one of ordinary skill in the art how to arrive at all of the co-crystal forms. Instead, the specification merely provides examples showing the fabrication of the particular co-crystals recited in claim 11, including carbamazepine and saccharin, and topiramate and 18-crown-6 co-crystals (see Examples 1-37, in particular.) Thus, while the specification provides guidance for forming the particular co-crystals specifically disclosed in the specification and recited in claim 11, the specification does not provide adequate guidance as to how one of

ordinary skill in the art could prepare all other crystals containing any API and co-crystal former.

8. The quantity of experimentation necessary: As the specification does not provide adequate guidance to allow one of ordinary skill in the art to readily determine the manufacturing conditions required to achieve crystallization of all of API/co-crystal formers, nor to determine which combinations of API and co-crystal former would even be capable of being recovered in crystal form, it is considered that one of ordinary skill in the art would have to engage in **undue experimentation** in order to be able to fully make and use the invention to the full extent of the claims.

In particular, as the parameters crucial to forming all of the API/co-crystal former crystals are not known, one of ordinary skill in the art would have to perform an exhaustive search to find all of those APIs and co-crystal formers, as well as all crystallization parameters, that are necessary to provide the crystal forms. To make all of the possible crystals, one of ordinary skill in the art would have to first have to select a particular API and co-crystal former combination, and then discover the means of achieving the crystalline form of the combination by performing numerous and exhaustive crystal manufacturing processes and making incremental changes in each manufacturing parameter, such as solvent and temperature parameters, to try and obtain the compounds in co-crystal form. If the components failed to crystallize, the crystal manufacturing process would have to be repeated, again with incremental

changes in parameters, to attempt to achieve a new crystal form. If a crystal were achieved, the crystal would have to be analyzed by X-ray diffraction or other method to determine whether hydrogen bonding existed in the crystal. The above procedure would have to be repeated numerous different times with a variety of different process parameters, as well as with different APIs and co-crystal formers, in order for one of ordinary skill in the art to discover all those co-crystal forms that fall within the scope of the claim, and thus to be able to fully make and use the invention commensurate with the full scope of the claim. Therefore, the skilled artisan would have to exercise **undue experimentation** to practice the instant invention.

Thus, the specification fails to provide sufficient support for the broad recitation of a co-crystal composition containing any solid API, in general, with any solid or liquid co-crystal-former, in general, in which the components are hydrogen bonded to each other. As a result, one of ordinary skill in the art would be required to perform an exhaustive search for the embodiments of the co-crystal compositions that are suitable for the practice of the invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for a search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the *Wands* factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in *undue experimentation* to make and use all of the co-crystal compositions encompassed by the instant claims, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 9-11 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by the article entitled "The Formation of Paracetamol (acetaminophen) Adducts with Hydrogen-Bond Acceptors" by Oswald et al, 2002, Acta Crystallographica Section B, Vol. B58, pages 1057-1066.

Oswald et al. teaches preparing crystal forms of paracetamol (i.e. acetaminophen), including adducts with 4,4'-bipyridine (see abstract, in particular.) Oswald et al. teaches that the compounds in the adduct are hydrogen bonded (see Section 3.3, in particular.) Accordingly, Oswald et al. teaches one of the specific co-

crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

Regarding claim 10, Oswald et al. teaches that the compounds can be used for the formation of tablets (see first full paragraph of Introduction on page 1057, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 9-10, 11 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by the article entitled "Crystal Engineering of Novel Co-Crystals of a Triazole Drug with 1,4-Dicarboxylic Acids" by Remenar et al, JACS, Vol. 125, pages 8456-8457, published on the web on June 21, 2003.

Remenar et al. teaches non co-crystals of itraconazole with 1,4-dicarboxylic acids including fumaric acid, succinic acid, and malic acid (see Table 1, in particular), and teaches that the co-crystals are hydrogen bonded (see paragraph bridging right and left hand columns on page 8456, in particular.) Accordingly, Remenar et al. teaches the

specific co-crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

Regarding claim 10, Remenar et al. teaches that the compounds are pharmaceutical solids for pharmaceutical uses (see first full paragraph of page 8456, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Claims 1-2, 9-10, 11 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by the article entitled "Crystal Engineering of the Composition of Pharmaceutical Phases: Multiple-Component Crystalline Solids Involving Carbamazepine" by Fleischman et al, Crystal Growth and Design, Vol. 3, No. 6, pages 909-919, published on the web on June 17, 2003.

Fleischman et al. teaches forming co-crystals of carbamazepine (CBZ) with benzoquinone, saccharin, nicotinamide, trimesic acid, 5-nitroisophthalic acid and adamantine-1,3,4,5-tetracarboxylic acid (see abstract, in particular.) Fleischmann et al. teaches that the resulting crystals contain hydrogen bonds (see Table 2, in particular.) Accordingly, Fleischman et al. teaches the specific co-crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

Regarding claim 10, Fleischman et al. teaches that the compounds contain CBZ as an active pharmaceutical ingredient (API), which has analgesic and anticonvulsant properties (see abstract and Introduction, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Claims 1-2, 9, 11 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by the article entitled "Crystal and Molecular Structure of a Complex of 18-Crown-6 with 6-chloro 7-sulfamido-3,4-dihydro-1,2,4-benzothiadiazine" by Dvorkin et al, Kristallografiya, 1990, Vol. 35, No. 3, pages 682-686 (English abstract.)

Dvorkin et al. teaches the preparation of a co-crystal of 18-crown-6 with 6-chloro 7-sulfamido-3,4-dihydro-1,2,4-benzothiadiazine (hydrochlorothiazide), and teaches that the hydrogen bonding of the crystal is described (see abstract, in particular.) Accordingly, Dvorkin et al. teaches the specific co-crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 9-10 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,559,293 to Almarsson et al, issued May 6, 2003.

Almarsson et al. teaches novel salts of topiramate and co-crystals thereof (abstract, in particular.) Almarsson et al. teaches that the co-crystals can be hydrogen bonded, and provides the specific co-crystal example of topiramate and caffeine (see paragraph bridging columns 14-15, in particular.) Thus, Almarrson et al. teaches a co-crystal composition comprising a solid API (topiramate) and a solid co-crystal former (caffeine), which are hydrogen bonded to one another, as in claim 1, and that has the functional groups as recited in claim 2.

Regarding claims 9 and 37, Almarsson et al. teaches the topiramate and caffeine co-crystal, and thus teaches the composition wherein the API is topiramate, as in claim 9, and teaches a crystal that is not one of those excluded by claim 37.

Regarding claim 10, Almarsson et al. teaches that the compounds are intended as pharmaceutically acceptable materials for the treatment of conditions such as tremors and seizures (see abstract, in particular), and thus anticipates providing the

compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Claims 1-2, 9-10, 11 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 03/074474 to Zaworotko et al, published September 12, 2003.

Zaworotko et al. teaches forming co-crystals of various pharmaceutical compounds, including acetaminophen/4,4'-bipyridine, phenytoin/pyridine, aspirin/4,4'-bipyridine, ibuprofen/4,4'-bipyridine, flurbiprofen/4,4'-bipyridine, among many others (see abstract and pages 7-9, in particular.) Zaworotko et al. teaches that the crystals contain hydrogen bonds (see pages 7-9, in particular.) Accordingly, Zaworotko et al. teaches the specific co-crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

Regarding claim 10, Zaworotko et al. teaches that the compounds are for pharmaceutical entities and contain at least one active pharmaceutical ingredient (see abstract and Introduction, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Claims 1-2 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0176335 to Scott L. Childs, published September 9, 2004.

Childs teaches novel cocrystals and methods of cocrystallization using the salt of an active agent (see abstract, in particular.) Childs teaches that the cocrystals are formed by providing strong hydrogen bond donor molecules to the crystal system (see paragraph 0006, in particular), and thus teaches forming a cocrystal of an API with a co-crystal former that is hydrogen bonded, as recited in claim 1. Childs provides the specific example of a co-crystal comprising fluoxetine HCl and succinic acid (see Examples 2 and 5, in particular), and thus teaches a crystal having a solid API and a solid or liquid co-crystal former (note that instant claim 11 recites succinic acid as a suitable co-crystal former for itraconazole), and thus meets the limitations of claim 1 and the co-crystal former functional group limitation of claim 2.

Regarding claim 10, Childs teaches that the composition is intended to include and active pharmaceutical ingredient (see abstract, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 9-11 and 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.7,078,526 to Remenar et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals of APIs and co-crystal formers, including the specific crystals listed in claim 11, such as itraconazole and tartaric acid, whereas the patented claims are to only the specific co-crystal that contains itraconazole and tartaric acid. Accordingly, the instant claims are obvious over the specific patented co-crystal, and thus are not patentably distinct over the 7,078,526 patent.

Claims 1-2 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 86-93 of copending Application No. 10/546,963, as published in U.S. Patent Application Publication No. 2007/0059356 to Almarsson et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, whereas the published claims are to co-crystal compositions having APIs and co-crystal formers with functional groups that allow for hydrogen bonding. Accordingly, the broader class of co-crystals as claimed is obvious over the co-crystals having the specific functional groups as in the published application, and the instant claims are not patentably distinct from those in the 2007/0059356 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 and 72-87 of copending Application No. 10/570,405, as published in U.S. Patent Application Publication No. 2007/0021510 to Hickey et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including modafinil and malonic acid, whereas the published claims are to co-crystal

compositions having modafinil as the APIs and co-crystal formers that hydrogen bond to one another, such as malonic acid. Accordingly, the broader class of co-crystals as claimed is obvious over the specific modafinil co-crystals as in the published application, and the instant claims are not patentably distinct from those in the 2007/0021510 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 66-72 of copending Application No. 10/551,014, as published in U.S. Patent Application Publication No. 2006/0223794 to Bourghol Hickey et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including olanzapine and nicotinamide, whereas the published claims are to the specific co-crystal compositions having olanzapine and nicotinamide as the co-crystal components. Accordingly, the broader class of co-crystals as claimed is obvious over the specific olanzapine co-crystals as in the published application, and the instant claims are not patentably distinct from those in the 2006/00223794 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-7, 16 and 18 of copending Application No. 10/926,842, as published in U.S. Patent Application Publication No. 2005/0070551 to Remenar et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including itraconazole and various acids such as succinic acid, fumaric acid and tartaric acid, whereas the published claims are to the specific co-crystal compositions having itraconazole and acids such as malonic acid, fumaric acid, tartaric acid, etc, as well as other co-crystal forms. Accordingly, the scope of the instant claims overlaps with that of the published application, and accordingly, the instant claims are not patentably distinct from those in the 2005/0070551 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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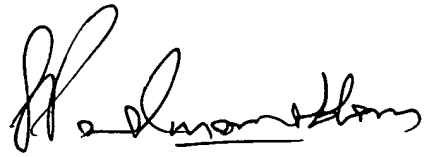

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